Translation

PATENT COOPERATION TREATY

PCT/JP2003/013528

PCT

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 3104WO0P	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP2003/013528	International filing date (*day/month/year*) 23 October 2003 (23.10.2003)	Priority date (*day/month/year*) 25 October 2002 (25.10.2002)
International Patent Classification (IPC) or national classification and IPC C07K 16/18, C12N 15/09, 5/10, C12P 21/08, A61K 39/395, A61P 9/00, 9/02, 9/04, 9/06, 9/12, 13/10, 13/12, 25/16, 25/18, 25/20, 25/22, 25/24, 25/28		
Applicant TAKEDA CHEMICAL INDUSTRIES, LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 25 November 2003 (25.11.2003)	Date of completion of this report 23 April 2004 (23.04.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

ational application No.
PCT/JP2003/013528

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the claims:

pages _____

pages _____, as originally filed

pages _____, as amended (together with any statement under Article 19

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the drawings:

pages _____

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRE[redacted]NARY EXAMINATION REPORT

International application No. [redacted] PCT/JP03/13528

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 22, 23

because:

☒ the said international application, or the said claims Nos. 22, 23 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

The subject matters of claims 22 and 23 relate to a method for treatment of the human body or a diagnostic method, which does not require an international preliminary examination by the International Preliminary Examining Authority in accordance with PCT Article 34 (4)(a)(i) and Rule 67.1(iv).

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 22, 23 .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRE[redacted]NARY EXAMINATION REPORT

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	7-17, 24	YES
	Claims	1-6, 18-21	NO
Inventive step (IS)	Claims		YES
	Claims	1-21, 24	NO
Industrial applicability (IA)	Claims	1-21, 24	YES
	Claims		NO

2. Citations and explanations

Document 1: EP, 1241479, A2 (ABC Armbruster Biochemicals), 18 September, 2002 (18.09.02), full text
Document 2: EP, 1136503, A1 (Takeda Chemical Industries, Ltd.), 26 September 2001, (26.09.01), full text
Document 3: WO, 01-04298, A1 (Takeda Chemical Industries, Ltd.), 18 January, 2001 (18.01.01), full text
Document 4: WO, 01-37780, A2 (Smithkline Beecham Corp.), 31 May, 2001 (31.05.01), full text

The subject matters of claims 1-6 and 18-21 do not appear to be novel or to involve an inventive step in view of documents 1-3 cited in the ISR.

Document 1 describes a monoclonal antibody and a polyclonal antibody against urotensin II having an amino acid sequence corresponding to the SEQ ID NOS: 1 and 9 of the present application, and also describes that the antibodies are used for detecting urotensin II. (Especially, see SEQ ID NOS: 2 and 1.)

Document 2 describes a monoclonal antibody and a polyclonal antibody against the peptide having an amino acid sequence corresponding to the SEQ ID NOS: 1-4 and 6 of the present application, and also describes that (1) the antibodies are used for detecting and determining the said polypeptide, and (2) the antibodies are also used as diagnostic agents for the diseases to which the said polypeptide relates. (Especially, see SEQ ID NOS: 22, 7, 8, 21 and 39, pages 55-63, the claims.)

Document 3 describes a monoclonal antibody and a polyclonal antibody against the peptide having an amino acid sequence corresponding to the SEQ ID NOS: 5 and 8 of the present application, and also describes that (1) the antibodies are used for detecting and determining the said polypeptide, and (2) the antibodies are also used as diagnostic agents for the diseases to which the said polypeptide relates. (Especially, see SEQ ID NOS: 5 and 27, pages 46-53 and the claims).

The subject matters of claims 1-21 and 24 do not appear to involve an inventive step in view of documents 1-4 cited in the ISR.

Document 4 describes the polypeptide having an amino acid sequence corresponding to the SEQ ID NO: 7 of the present application as human urotensin II analogue. (Especially, see SEQ ID NO: 11.)

Documents 1-4 belong to the same technical field in view of urotensin II and its method of usage. So, a person skilled in the art could have easily conceived of (1) obtaining an antibody against the peptide in the invention described in document 4 based on the inventions described in documents 1-3 and (2) using the antibody for detecting antigens and diagnosing the diseases to which urotensin II analogue relates.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of : V.2

Furthermore, it is also publicly known due to documents 1-4 that urotensin II relates to various diseases. So, a person skilled in the art could have easily (1) obtained a specific antibody capable of neutralizing the function of urotensin II for the purpose of preventing and curing the diseases to which urotensin relates, based on the inventions described in documents 1-4, and (2) used the obtained antibody as a preventive/remedy for the diseases to which urotensin II relates.